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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/821,821 | 03/29/2001 | Andrew A. Welcher | 01017/36938A | 6210 |

4743 7590 10/13/2005

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| EXAMINER | |
|---|---|
| MERTZ, PREMA MARIA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | |

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/821,821 | WELCHER ET AL. | |
| | Examiner | Art Unit | |
| | Prema M. Mertz | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4-8,10,51-55,70 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-8, 10, 51-55, 70, 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 2-4, 9, 11-50, 56-69, 71 have been canceled previously.. Previously presented claims 1, 4-8, 10, 51-55, 70, 72 are under consideration.

2. Receipt of applicant's arguments and amendments filed on 9/14/2005 is acknowledged.

3. Applicant's arguments filed on 9/14/2005 have been fully considered but were non-persuasive. The issue remaining is restated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim rejections-35 USC § 101***

5. Claims 1, 4-8, 10, 51-55, 70, 72 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02), pages 3-9 of the previous Office action (12/4/03), pages 2-4 of the previous Office action (7/13/2004) and pages 2-7 of the previous Office action (3/14/2005).

The claims are directed to an isolated nucleic acid of amino acid sequence set forth n SEQ ID NO:1. In Example, 3 page 112 lines 13-18, of the specification discloses that the claimed nucleic acids are preferentially expressed in testis cells. The invention encompassed by these claims has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published on 1/5/01, 66 FR 1092.

The instant application has provided a description of an isolated nucleic acid but does not disclose a specific and substantial biological role for this nucleic acid or the significance of this

nucleic acid. The mere identification that the nucleic acid is expressed preferentially in human testes is not sufficient to impart any particular utility to the claimed polynucleotide without any information as to the specific properties of this polynucleotide. Only in their subsequent arguments have Applicants asserted that the claimed polynucleotide can be used as a specific marker for metastasized testicular cancer cells. There is no disclosure of this potential use in the application as filed. Furthermore, since the asserted utility (argued only in Applicants arguments) is not present in a ready-to-use, real-world application, the asserted utility is not substantial.

The specification asserts the following as utilities for the claimed polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1:

1. use of the nucleic acid to treat, prevent, ameliorate and detect disorders;

2. diagnosing a pathological condition or susceptibility to a pathological condition; and

3. methods of identifying antagonists or agonists of CD20/IGE-receptor like biological activity.

1. *use of the nucleic acid to treat, prevent, ameliorate and detect disorders*

This asserted utility is not specific or substantial. The specification on page 8, lines 18-28, discloses:

"The invention encompasses diagnosing a pathological condition or the susceptibility to a pathological condition in a subject caused by or resulting from abnormal (i.e. increased or decreased) levels of CD20/IgE-receptor like polypeptide comprising determining the presence or amount of expression of the CD20/IgE-receptor like polypeptide in a sample and comprising the level of said polypeptide in a biological, tissue or cellular sample from either normal subjects or

the subject at an earlier time, wherein susceptibility to a pathological condition is based on the presence or amount of expression of the polypeptide."

The specification also discloses on page 112, lines 13-18, discloses that the claimed nucleic acid is predominantly expressed in human testes, pancreas, a colon carcinoma cell line (CX-1), and an ovarian carcinoma cell line (GI-102). Therefore, the specification discloses that the claimed nucleic acid is not "exclusively" expressed in the testis but "predominantly" expressed in the testis. No Northern blot has been provided to show the basal level of expression of this nucleic acid in the pancreas or testis, and how this expression compares to the expression of the claimed nucleic acid in the colon carcinoma cell line (CX-1), and the ovarian carcinoma cell line (GI-102). There is no recitation in the specification of the use of this nucleic acid as a marker for metastasized testicular cancer cells. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

2. *diagnosing a pathological condition or susceptibility to a pathological condition*

This asserted utility is not specific or substantial. Since any and all nucleic acids expressed in testis tissue can be used in a research setting to detect the presence of testis tissue, the asserted utility is not specific. Furthermore, the specification does not disclose how this specific nucleic acid can be used in diagnosis since no differential expression has been shown with the claimed nucleic acid in normal and metastasized testis tissue, and therefore further significant research would be required on one skilled in the art to determine how to use the claimed polynucleotide. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

3. *methods of identifying antagonists or agonists of CD20/IGE-receptor like biological activity*

This asserted utility is not specific or substantial. Since the same generic assays can be performed with any polynucleotide encoding a polypeptide with CD20/IGE-receptor like biological activity, the asserted utility is not specific to the claimed polynucleotide (SEQ ID NO:1) (see specification, page 9, lines 30-34; page 10, lines 1-7). Also, since the specification does not disclose how the specific nucleic acid of nucleotide sequence set forth in SEQ ID NO:1 can be used, significant further research would be required of a person skilled in the art to determine how to use the claimed polynucleotide. Since the asserted utility is not present in a ready-to-use, real-world application, the asserted utility is not substantial.

Applicants argue that the assertion of utility as a marker for metastasized testicular cancer cells is not dependent on a differential level of expression in cancerous versus healthy cells of the testis, that the marker identifies a testicular cell and that the asserted utility simply does not require a detectable difference in expression in cancerous versus healthy testicular cells and there is, therefore, no need for comparative studies of cancerous and healthy testicular cells to support that utility. However, contrary to Applicants arguments, in the specification as filed, there is absolutely no disclosure that the claimed nucleic acid ca be used in the identification of cancerous testicular cells that have metastasized. Furthermore, since the claimed nucleic acid is also predominantly expressed, for example in pancreas, this asserted utility (even if it was disclosed in the specification as filed) is not specific because one of skill in the art would not know if the metastasis was due to metastasized testicular or metastasized pancreatic cells.

Therefore, the claimed nucleic acid has not been shown by Applicants to have a function as a specific marker for human testis, including metastasized testicular cells, due to lack of selective expression only in testicular cells.

Applicants argue that they have provided a copy of a reference by Kinkade (1999) disclosing that testicular tumors metastasize via the lymphatic system. However, contrary to Applicants arguments, the issue here is not that the Examiner doubts the capacity of testicular cells to metastasize, but as argued by the Examiner supra, this utility was never disclosed in the specification as originally filed. A specification has to be complete and disclose a credible, specific, substantial and well-established utility as filed. Furthermore, even if it was disclosed in the specification as originally filed, the predominant expression of the claimed nucleic acid in pancreas, does not meet the requirements of 35 USC 101 for a specific and substantial asserted utility or a well-established utility. An asserted utility must meet the three-pronged test of being credible, specific and substantial. The utilities for the claimed nucleic acid recited in the instant specification are generic utilities that fail to satisfy all three prongs. The skilled artisan would have to conduct significant further research to determine the particular functions of the instantly claimed nucleic acid in order to identify a specific and substantial utility for the nucleic acid. Therefore, the asserted utilities in the instant specification are not specific or substantial because one of skill in the art, as of the filing of the instant application, would not have discerned the biological role of the claimed nucleic acid, because there is no disclosure suggesting what type of biological role is played by the claimed nucleic acid.

**The utility is neither specific nor substantial**

The credibility of any general utility asserted in the instant specification (see pages 8-9) is not being questioned. The assertion that the claimed nucleic acid can be used to screen for antagonists or agonist of CD20/IgE-receptor like biological activity (page 9, lines 30-34 of the specification) is not a specific assertion of utility. Also, the specification does not state what the role of the protein encoded by the claimed nucleic acid is and what types of functions or disorders the protein is involved in. The specification provides no nexus between nucleic acid expression and any specific disease or a change in expression of the claimed nucleic acid with any specific disease. Since significant further research would be required before the claimed nucleic acid could be used, the asserted utility is not substantial.

Applicants argue that the Office has the burden to provide evidence showing that the utility is not credible. The Revised lnterim Utility Guidelines Training Material (herein after "Training Material") states that "an assay method for identifying compounds that themselves have a 'substantial utility' define a 'real world' context of use." See page 6 of the Training Material. However, contrary to Applicants assertion, there is no issue with the credibility of the asserted utility. The issue is that the assertion that the claimed nucleic acid can be used in an assay to identify "possible" agonist and antagonists is not specific or substantial. The specification only asserts non-specific roles of nucleic acids encoding receptors. If the specification had asserted that the claimed nucleic acid is up-regulated in testicular cancer, then the assertion of utility would have been specific. Unfortunately, such a disclosure is not in the specification as originally filed.

The specification merely states that the claimed nucleic acid is predominantly expressed in the pancreas and in the testis. It does not characterize the role of the nucleic acid in these tissues. Therefore, the skilled artisan would have to conduct further experiments to determine the role of the claimed nucleic acid in these tissues. Is the claimed nucleic acid up-regulated or down regulated in diseases of the testis or pancreas? Without this information, the skilled artisan would not know if it was desirable to identify drugs that agonize or antagonize the protein encoded by the claimed nucleic acid as treatment for disorders of the pancreas or testis. Thus the specifications assertion of generic utilities is credible and this credibility has never been questioned but the assertion of the role of the claimed nucleic acid is not specific or substantial.

In conclusion, the specification fails to provide an assertion of a specific and substantial utility for the claimed nucleic acid and there is no well-established utility for the claimed nucleic acid.

***Claim rejections-35 USC § 112, first paragraph***

6. Claims 1, 4-8, 10, 51-55, 70 and 72 are also rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02), pages 3-9 of the previous Office action (12/4/03), pages 2-4 of the previous Office action (7/13/2004) and pages 2-7 of the previous Office action (3/14/2005).

Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Conclusion***

No claim is allowed.

Claims 1, 4-8, 10, 51-55, 70 and 72 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
October 3, 2005